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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,808	02/22/2002	Doron Kreiser	BEL1030U	2056

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EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,808	KREISER ET AL.	
	Examiner	Art Unit	
	Navin Natnithithadha	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12,13 and 15-21* is/are rejected.

7)☒ Claim(s) *10,11 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarrine, US 4,360,016 A, in view of Levy et al, US 6,332,888 B1, and further in view of Satterwhite, US 3,587,591 A.

Claims 1 and 2: Sarrine discloses a device 10 for measuring fetal blood pH (see col. 1, lines 10-27), comprising: a lancet 40 extendable from a distal end of the device for incising tissue (see fig. 4 below); and a capillary 30 at the distal end of the device for collecting a sample of blood for pH analysis (see fig. 1 and 7 below).

Fig-1

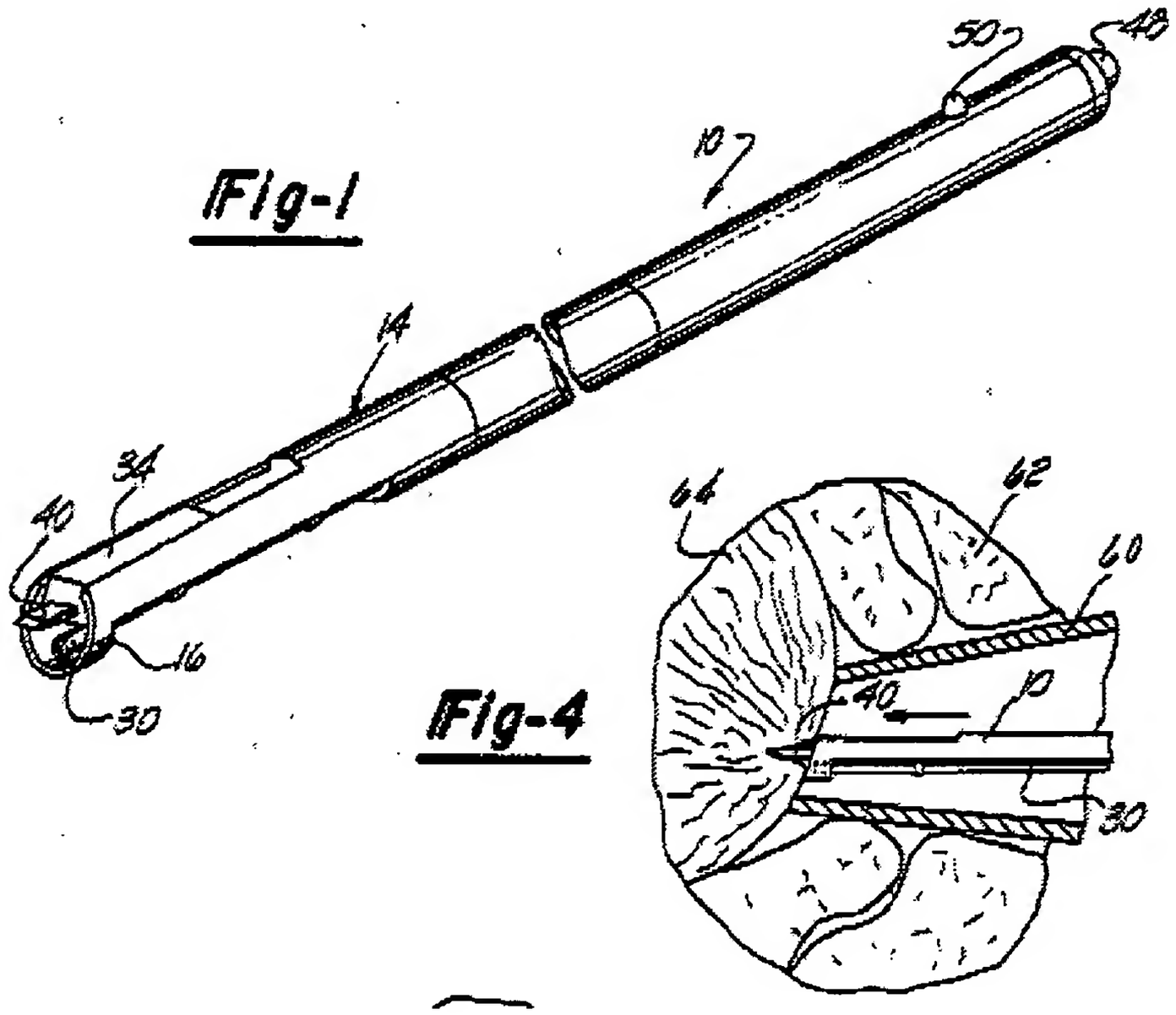

Fig-4

Sarrine discloses the capillary 30 is in a fixed position (see col. 2, lines 59-62) and not extendable from the distal end of the device 10. After the incision of the tissue, blood flows downward and into the fixed capillary tube (see fig. 7 below).

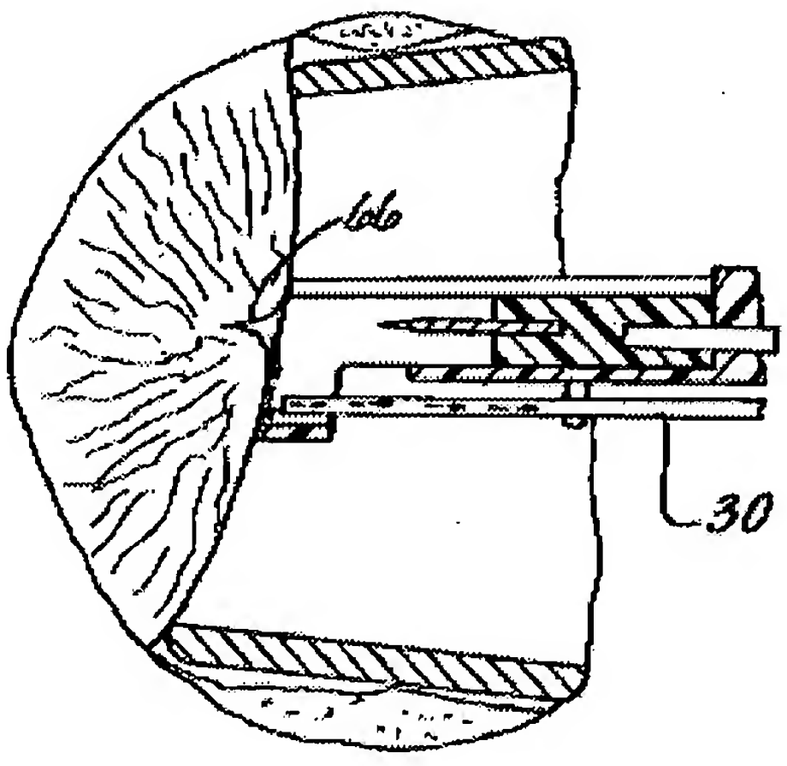

Fig-7

However, Levy et al discloses a device comprising: a lancet 414 extendable (ejectable) from a distal end of the device for incising tissue (see fig. 64 below and col. 21, lines 46-55); and a capillary 402 extendable (ejectable) from the distal end of the device for collecting a sample of blood (see col. 21, lines 25-35). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Sarrine's device to have both a lancet and a capillary extendable from the distal end of the device in order to effectively sample blood from any position of the device.

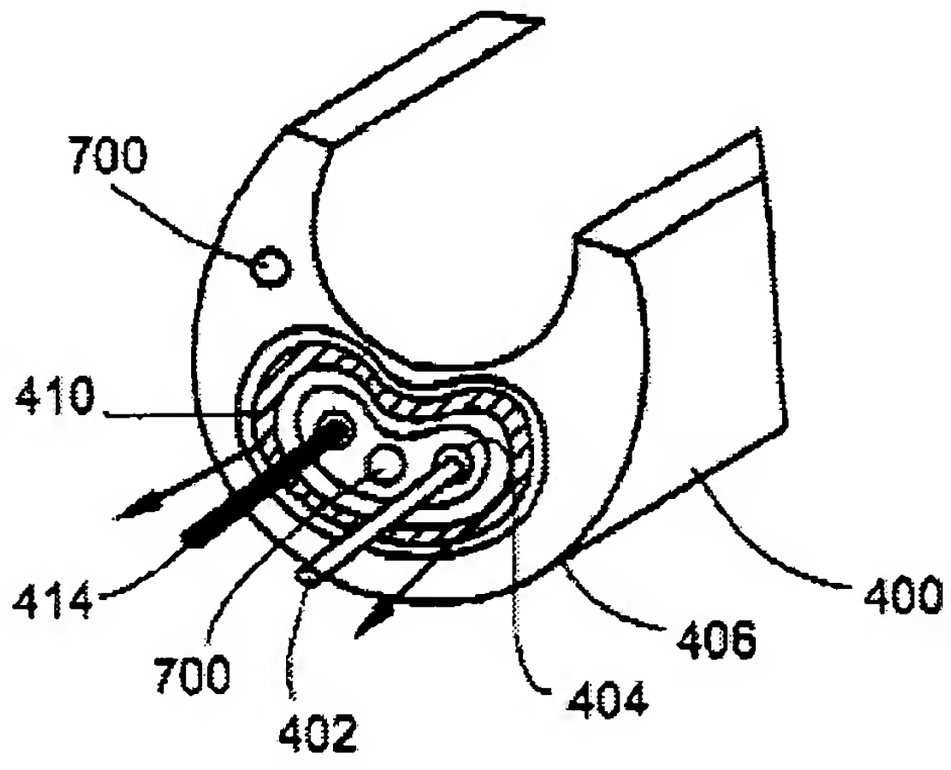

Fig. 64

Sarrine discloses a handle type member 14 and not a means for mounting the device to an operator's hand in the form of a surgical glove. However, Salterwhite discloses a device comprising: a means 22 for mounting the device to an operator's hand in the form of a surgical glove 22 (see figs. 1 and 5); and a lancet 42 extendable from a distal end of the device for incising tissue. It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Sarrine's device to be mounted

on an operator's hand in the form of a surgical glove in order to more easily place a lancet at an incision site.

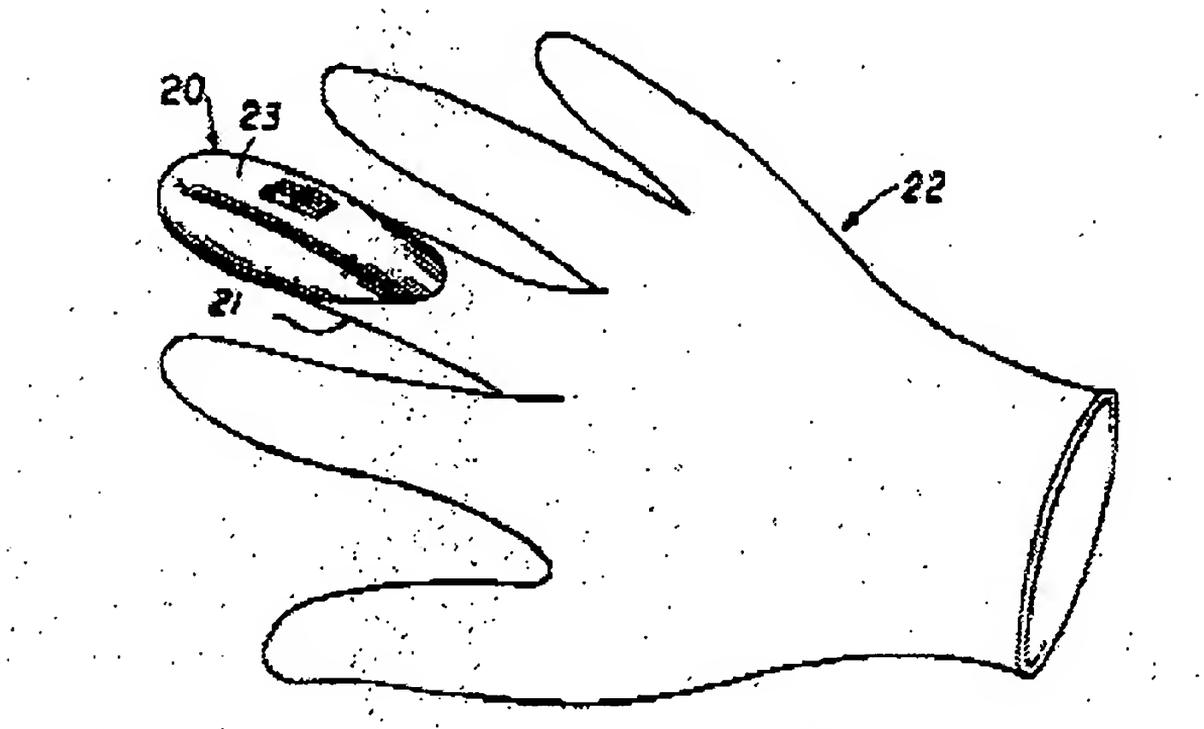

Fig. 1

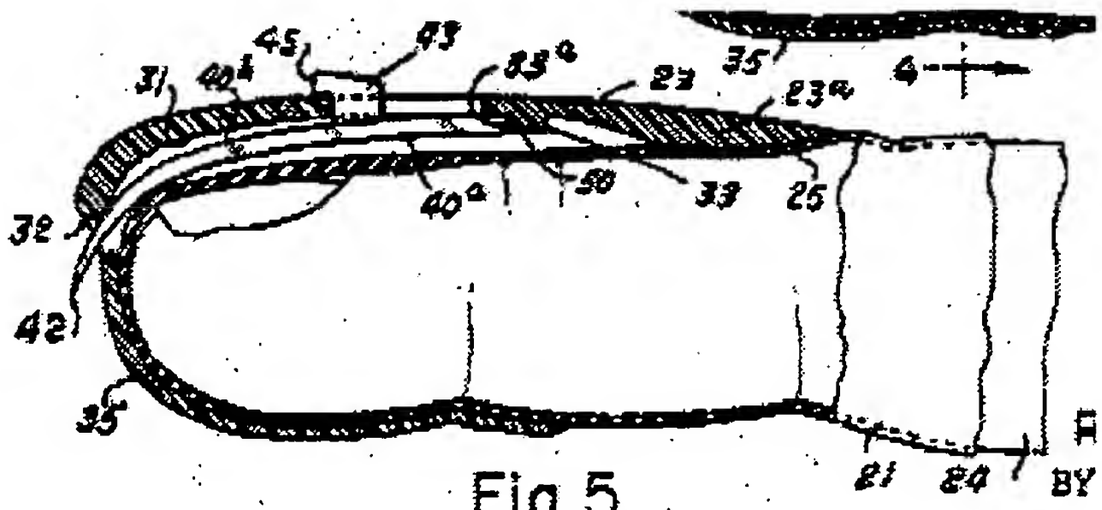

Fig. 5

2. Claims 1, 3-9, 12, 13, and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarrine, US 4,360,016 A, in view of Levy et al, US 6,3325,888 B1. Claims 1, 3, and 4: Sarrine discloses a device 10 for measuring fetal blood pH (see col. 1, lines 10-27), comprising: a lancet 40 extendable from a distal end of the device for incising tissue (see fig. 4 below); and a capillary 30 at the distal end of the device for collecting a sample of blood for pH analysis (see fig. 1 and 7 above). Sarrine

discloses the capillary 30 is in a fixed position (see col. 2, lines 59-62) and not extendable from the distal end of the device 10. After the incision of the tissue, blood flows downward and into the fixed capillary tube (see fig. 7 above). Also, Sarrine discloses a handle type member 14 and not a means for mounting the device to an operator's hand in the form of a finger cot or a finger ring. However, Levy et al discloses a device (see fig. 1 above) comprising: a means 4 for mounting the device to an operator's hand in the form of a finger cot (thimble-like finger grip) 4 (see fig. 1 below and col. 13, lines 25-30) or a finger ring 400 (see fig. 63 below and col. 21, lines 11-32); a lancet (needle or puncturing device) 8/414 extendable from a distal end of the device for incising tissue (see col. 21, lines 46-55); and a capillary 402 extendable from the distal end of the device for collecting a sample of blood (see col. 21, lines 25-35). It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine Sarrine's device with that of Levy et al's device in order to more easily place a lancet and capillary at an incision site.

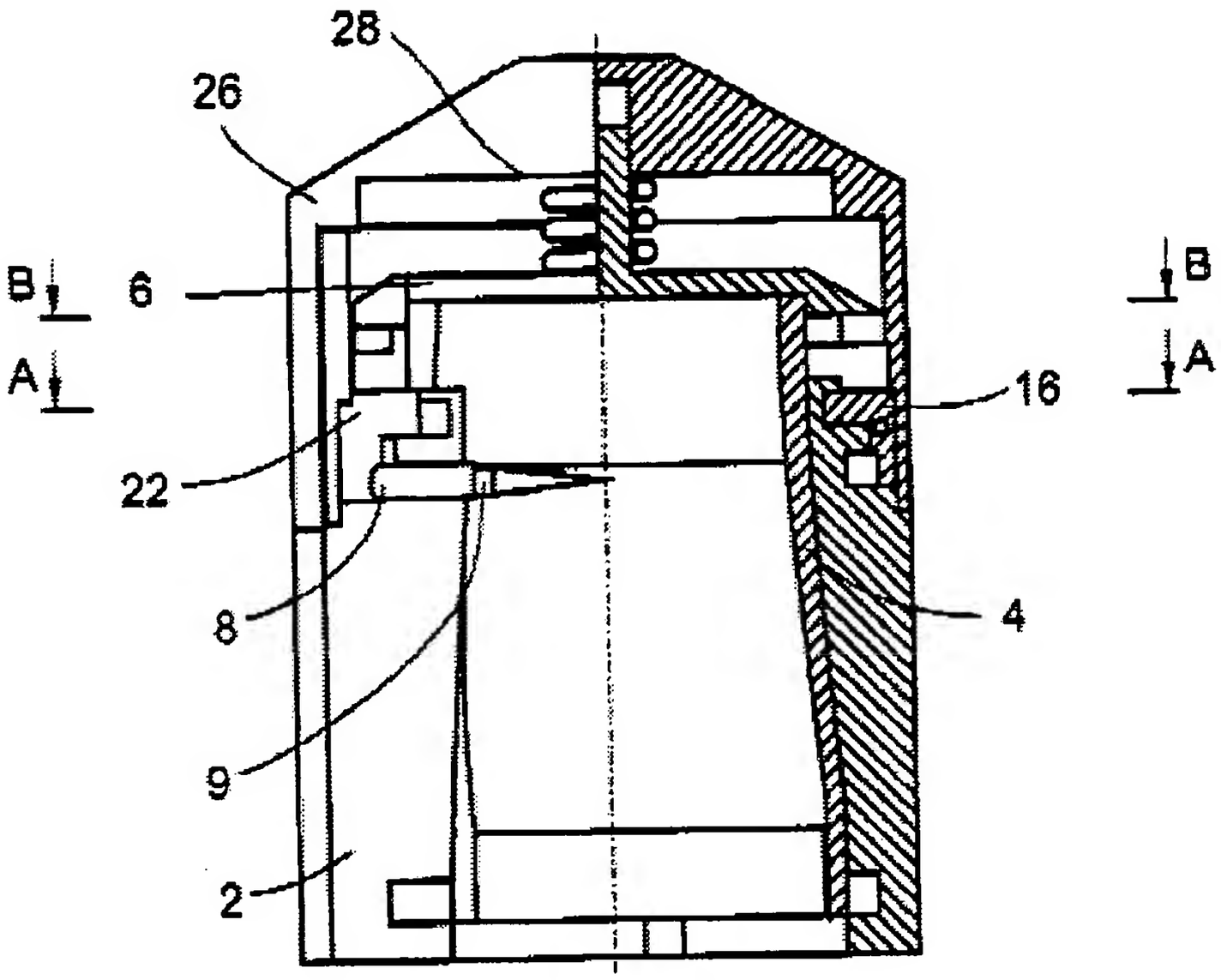

Fig. 1

Fig. 62

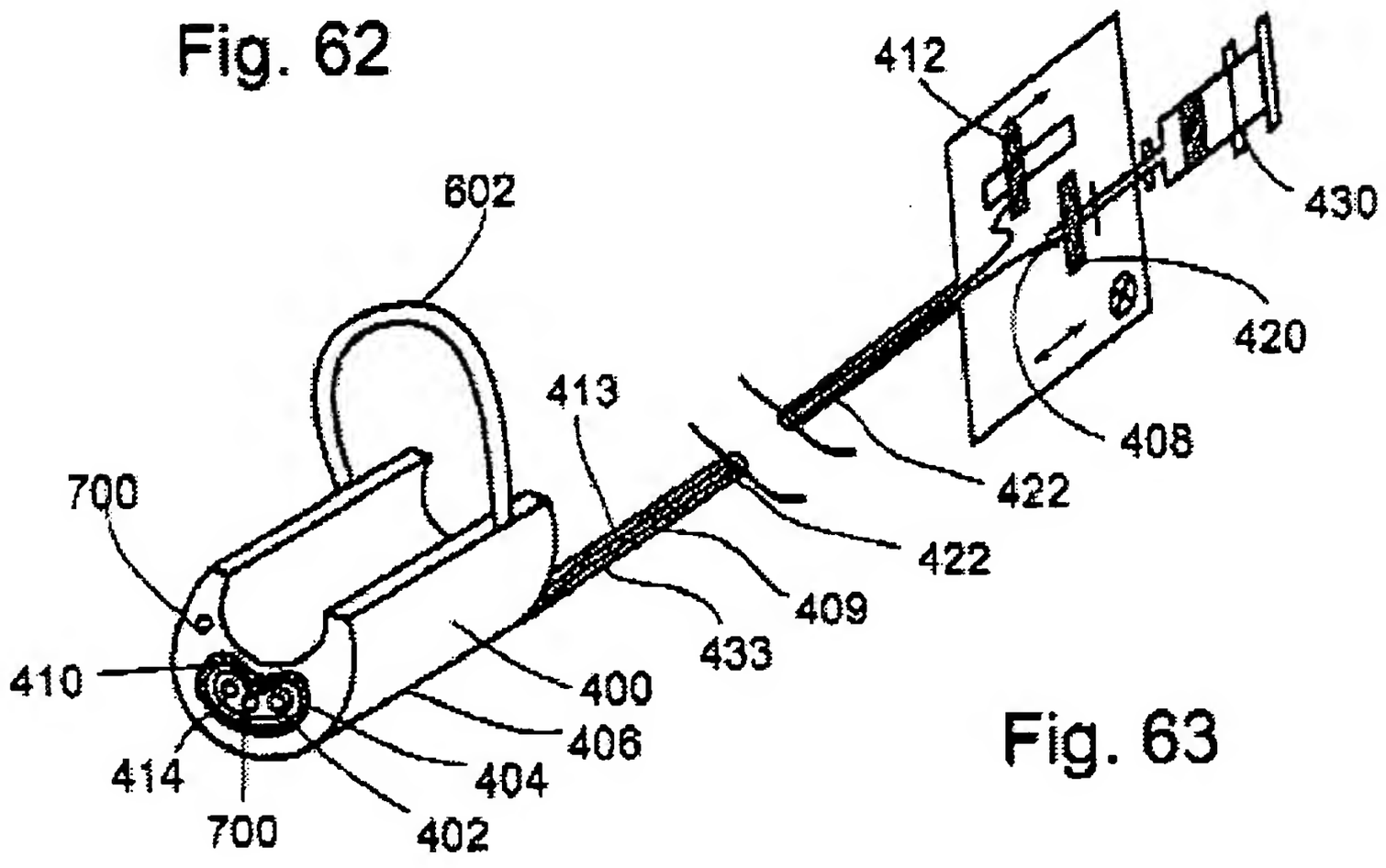

Fig. 63

Claims 5 and 7: Levy et al discloses a lancet (puncturing device) 414 and capillary 402 are slidably (ejectably) mounted in a guide tube (sleeve) 410 (see fig. 64 above). The guide tube 410 is shown in figure 64 as being one body having two tubes, in which both tubes can be considered a lancet guide tube and a capillary guide tube.

Claims 6 and 8: Levy et al discloses the lancet 414 and the capillary 402 are connected by a capillary actuator rod (first mechanism) 408 to a capillary actuator (translating actuator) 420 located at a proximal end of the guide tube (sleeve) 410 (see col. 21, lines 25-35 and lines 46-55).

Claim 9: Levy et al discloses the capillary is configured to be withdrawn from a proximal end of the of the capillary guide tube (see col. 21, lines 25-33 and col. 22, lines 10-13).

Claims 12, 13, and 15: Sarrine discloses a means (collar) 16 (or endoscope 60) is capable of isolating a distal region of the device from a surrounding region (see col. 2, lines 43-50 and lines 59-68), which is in the form of an everting bell-shaped member or expandable funnel member (see figs. 1 and 4 above). The collar or endoscope 60 can be considered an everting bell-shaped member or expandable funnel member.

Claim 16: Levy et al discloses a motorized actuator 420 for sequentially advancing (translating) the lancet and the capillary (see col. 21, lines 25-35 and lines 46-55).

Claim 18: Sarrine discloses a device 10 for measuring fetal blood pH (see col. 1, lines 10-27), comprising: a lancet 40 extendable from a distal end of the device for incising tissue (see fig. 4 below); and a capillary 30 at the distal end of the device for

collecting a sample of blood for pH analysis (see fig. 1 and 7 above). Sarrine discloses the capillary 30 is in a fixed position (see col. 2, lines 59-62) and not extendable from the distal end of the device 10. After the incision of the tissue, blood flows downward and into the fixed capillary tube (see fig. 7 above). Also, Sarrine discloses a handle type member 14 and not a means for mounting the device to an operator's hand in the form of a finger cot. However, Levy et al discloses a device (see fig. 1 below) comprising: a lancet and capillary guide tube (sleeve) 410; a lancet (needle or puncturing device) 8/414 slidably mounted in the guide tube 410 and connected by a lancet actuator rod (first mechanism) 408 to a lancet actuator (translating actuator) 420 located at a proximal end of the guide tube 410, wherein the lancet 414 is selectively extendable from a distal end of the lancet guide tube for incising tissue (see col. 21, lines 46-55); a capillary 402 slidably mounted in the guide tube 410 and connected by a capillary actuator rod (first mechanism) 408 to a lancet actuator (translating actuator 420 located at a proximal end of the guide tube 410, wherein the capillary 402 is selectively extendable from a distal end of the capillary guide tube for collecting a sample of blood (see col. 21, lines 25-35); and a means 4 for mounting the device to an operator's hand in the form of a finger cot (thimble-like finger grip) 4 (see fig. 1 below and col. 13, lines 25-30) or a finger ring 400 (see figs. 63 and 64 and col. 21, lines 11-32). It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine Sarrine's device with that of Levy et al's device in order to more easily place a lancet and capillary at an incision site.

Claim 19: Sarrine discloses a means 16 capable of isolating a distal region of the device from a surrounding region (see col. 2, lines 43-50 and lines 59-68).

Claim 20: Levy et al discloses a motorized actuator 420 for sequentially advancing (translating) the lancet and the capillary (see col. 21, lines 25-35 and lines 46-55).

Claim 21: Sarrine discloses a method for measuring fetal blood pH, comprising: inserting a pH device in proximity of a presenting part of a fetus in parturition (see col. 1, lines 10-27 and fig. 4 above); isolating (by collar 16 or endoscope 60) a region adjacent to a distal end of the pH device from a surrounding region (see fig. 4); advancing a lancet from the distal end of the device and incising tissue in the presenting part of the fetus; and collecting a sample of blood using a capillary from the incised tissue for pH analysis. Sarrine does not disclose the method comprising inserting a hand-mounted pH device and advancing a capillary from the distal end of the pH device. However, Levy et al discloses a method comprising: inserting a hand-mounted device into a body location; advancing (translatably ejecting) a lancet 414 (see col. 21, lines 46-55); and advancing (translatably ejecting) a capillary 402 from the distal end of the device and collecting a sample of blood from an incised tissue (see col. 21, lines 25-35). It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine Sarrine and Levy et al in order to more easily place a lancet and capillary at an incision site.

3. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarrine, US 4,360,016 A, in view of Levy et al, US 6,3325,888 B1, and further in view of Sarrine, US 4,350,147 A.

Claim 17: Claim 1 is anticipated under 35 U.S.C. 103(a) as discussed above. Neither, Sarrine nor Levy et al disclose a light source for illuminating a region distal to the device. However, Sarrine '147 discloses a light source 44 for illuminating a region distal to the device. It would be obvious for one of ordinary in the art at the time the invention was made to modify Sarrine's '016 device to have a light source in order to aid in viewing the operation of the device as suggested by his other patent '147 in column 3, lines 59-62.

Allowable Subject Matter

4. Claims 10, 11, 14, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter:

Claims 10 and 11: The prior art does not disclose claim 1 including: the capillary has a distal end configured as a capillary bulb and a pH electrode positioned within the capillary bulb.

Claim 14: The prior art does not disclose claim 12 including: the means for isolating a distal region of the pH measuring device from a surrounding region is in the form of an inflatable balloon member.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,048,352 A and US 5,951,492 A discloses a blood fluid sampling device with a capillary tube 92 and a lancing 96 extendable from the distal end of the device.

US 6,058,321 A discloses a fetal blood pH measuring device with both a capillary and a lancet integral 190 with each other and extendable from the distal end of the device.

US 4,660,570 A discloses fetal blood sampling device with a lancet 18 within a capillary tube 48.

US 4,441,510 A discloses a fetal monitoring device with separated lancet 16 and capillary tube 14.

US 3,685,509 A discloses a fetal blood sampling device with a lancet 13 and capillary tube 8 extendable from the device.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (703) 305-2445. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Navin Natnithithadha
Patent Examiner
GAU 3736
June 8, 2004

MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER